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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/580,287	05/30/2000	Yuhpyng L. Chen	PC8605D	1655

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EXAMINER
JONES, DWAYNE C

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 06/19/2002 7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/580,287	Applicant(s) CHEN, YUHPYNG L.	
	Examiner Dwayne C Jones	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *16-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *16-29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of Claims

1. Claims 1-29 are pending.

2. Claims 1-15 are elected and rejected.

3. Claims 16-29 are non-elected and withdrawn from further consideration.

Election/Restrictions

4. Applicant's election with traverse of Group I, corresponding to claims 1-15, in Paper No. 6 is acknowledged. In addition, the compound of butyl-[2,5-dimethyl-7-(2,4,6-trimethylphenyl)-6,7-dihydro-5H-pyrrrolo[2,3-d]pyrimidin-4-yl]-ethylamine was elected as a species as well as the disorder of depression, however these compounds were found in the prior art. The traversal is on the ground(s) that Groups I and II should be examined together. This is not found persuasive because the plethora of ailments and conditions of Group II can be treated with compounds other than those disclosed in Group I, such as with Prozac.

5. The requirement is still deemed proper and is therefore made FINAL.

Oath/Declaration

6. A new oath or declaration is required because the reference to Serial No. 09/254,387 in the declaration has an improper filing date of June 6, 1995 instead of March 4, 1999. The wording of an oath or declaration cannot be amended. If the wording is not correct or if all of the required affirmations have not been made or if it has

not been properly subscribed to, a new oath or declaration is required. The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons support this rejection. First, the variable of "Z" is defined but not listed in the compound of formula II. Second, when the variable of "Z" is defined as, "$N(C_1\text{-}C_2$ alkyl), $NC(O)CF_3$ or $C(R_{13}R_{14})$" each of these three groups have incomplete valenceies. Third, when the variables of R_1, R_2 are $C_1\text{-}C_6$ alkyl, $C_1\text{-}C_6$ alkylene, $C_5\text{-}C_8$ cycloalkyl, $C_5\text{-}C_8$ cycloalkylene and $C_5\text{-}C_8$ heterocycloalkyl moieties, it is further stated that "R_1 may optionally independently contain form one to three double or triple bonds." In addition, when the variables of R_4 and R_5 are alkyl and alkylene groups, it is stated that these groups "may optionally independently contain one or two double or triple bonds." Also, when the variable of R_6, R_{16}, R_{17} have a $C_1\text{-}C_4$ alkyl substituent which "may optionally contain one double or triple bond." Moreover, with variables R_{24} and R_{25} the $C_4\text{-}C_8$ heterocycloalkyl groups can be substituted with $C_1\text{-}C_4$ alkyl which can further be "optionally contain one or two double or triple bonds".

However, the fact that alkyl and cycloalkyl groups can only possess single bonds, not double and triple bonds, presents ambiguity to the claim. The variable of R_4 on line 2 of page 136 is defined as the substituent of "CH_2OF_3" which is causes indefiniteness because the valencey of fluorine is exceeded. In addition, the variable of R_4 on line 3 of page 136 is defined as $C{=}NOR_{24}$. However, the valencey for the carbon atom of $C{=}NOR_{24}$ is incomplete and renders the claim vague and indefinite. The variable of R5 on line 16 on page 136 for the group "$CO(NOR_{22})R_{23}$" has incomplete valency. The variable of R_5 on line 20 of page 136 is defined as the variable of "nitro halo". It appears that a comma is missing between these two substituents. Also, the variable of R_5 is redefined as R^5, which is inconsistent with the variable listed in formula II. All of these issues are unclear and thus render the claims vague and indefinite.

9. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claims 1-15 recite the limitation for the variable of R_2 that "the C_5-C_8 cycloalkyl, C_5-C_8 cycloalkylene, and C_5-C_8 heterocycloalkyl" in lines 19-20 on page 135. There is insufficient antecedent basis for this limitation in the claim.

11. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since

the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation "C_1-C_4 haloalkyl", and the claim also recites "especially CF_3, CHF_2, CF_2CF_3 or CH_2CF_3" which is the narrower statement of the range/limitation.

13. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

14. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to

whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 14 recites the broad recitation "inflammatory disorders", "phobias", "pain perception", "mood disorders", "depression", "neurodegenerative diseases", "eating disorders", "addictions", "neuronal damage", "cerebral ischemia", "immune dysfunctions", "stress induced immune dysfunctions" and the claim also recites "such as rheumatoid arthritis", "including social phobia", "such as fibromyalgia", "such as depression", "including major depression", "such as Alzheimer's disease", "such as anorexia", "including dependencies", " including cerebral ischemia", "for example cerebral hippocampal ischemia", "including stress induced immune dysfunctions", "including porcine stress syndrome", respectively which are the narrower statements of the ranges/limitations.

15. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

16. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as

to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 15 recites the broad recitation "inflammatory disorders", "pain perception", "mood disorders", "depression", "neurodegenerative diseases", "eating disorders", "immune dysfunctions", "in a mammal" and the claim also recites "such as rheumatoid arthritis", "such as fibromyalgia", "such as depression", "including major depression", "such as Alzheimer's disease", "such as anorexia ", "including stress induced immune dysfunctions", "including a human", respectively, which are the narrower statements of the ranges/limitations.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

18. Claims 1-15 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Chen of WO 95/33750 possessing a publication date of December 14, 1995. Chen

teaches of the corticotropin-releasing factor antagonist compounds and pharmaceuticals of formula (II), (see abstract and claims 1-14).

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

20. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

21. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaefer et al. Schaefer teach of the compounds of formula III, (see abstract). The claims differ from the reference by having a primary amino group at the position which corresponds to the instant invention's variable of B, which has the group NR_1R_2 wherein R_1 is a lower alkyl group and R_2 is hydrogen or lower alkyl. More specifically, the claims differ from the prior art by having a methyl substituent at applicant's variable of R_1 in lieu of the hydrogen atom taught by Schaefer et al. One having ordinary skill in the art would have been motivated to select the claimed compound with the expectation

that substitution of a methyl substituent for a hydrogen atom of an amino group would not significantly alter the properties of the compound of the reference due to the close structural similarity of the compounds.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

DWAYNE C. JONES
PRIMARY EXAMINER

Tech. Ctr. 1614
June 13, 2002